IN THE UNITED STATES DISTRICT COURT
NORTHEN DISTRICT OF OHIO
EASTERN DIVISION

LIFELINK PHARMACEUTICALS, INC.,	)	CASE NO. 5:07-cv-00785-JG
	)	
Plaintiff,	)	JUDGE JAMES S. GWIN
	)	MAGISTRATE JUDGE GALLAS
v.	)	
	)	**WELLNESS INDUSTRIES, INC.'S AND MINERAL SCIENCES, LLC'S ANSWER TO SECOND AMENDED COMPLAINT AND COUNTERCLAIM**
NDA CONSULTING, INC., et al.,	)	
	)	
Defendants.	)	

Defendants, Wellness Industries, Inc. ("Wellness") and Mineral Sciences, LLC ("Mineral Sciences") (hereinafter referred to collectively as "Defendants"), by and through their undersigned counsel, hereby file this, their Answer to Plaintiff's Second Amended Complaint and Counterclaim and state:

THE PARTIES

1. Defendants admit the first two sentences of paragraph 1. Defendants are without sufficient information or knowledge to admit or deny the allegations contained in the second sentence of Paragraph 1. Defendants deny the last sentence of paragraph 1. In particular, Defendants deny that any product practicing the '045 Patent has ever been sold in the marketplace or that the specific product names listed refer to products practicing the '045 Patent. Unless otherwise stated, for purposes of this Answer, Defendants will interpret the term "Product" to mean a product practicing the '045 Patent.

2. Admitted.

3. Admitted.

4. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 4.

5. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 5.

6. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 6.

7. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 7.

8. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 8.

9. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 9.

10. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 10.

11. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 11.

12. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 12.

13. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 13.

14. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 14.

15. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 15.

16. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 16.

17. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 17.

18. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 18.

19. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 19.

20. Defendants admit the first and second sentences of Paragraph 20. Defendants deny the third sentence of Paragraph 20 to the extent that it implies that a license directly from Plaintiff would be required to manufacture, distribute, market, and/or sell the Product.

21. Defendants admit the first sentence of Paragraph 21. Defendants deny the second sentence of Paragraph 21 to the extent that it implies that a license directly from Plaintiff would be required to manufacture, distribute, market, and/or sell the Product. Defendants also deny the second sentence of Paragraph 21 to the extent that the term "manufactures" implies something more than processing of the raw ingredients.

22. Defendants deny the first sentence of Paragraph 22. Defendants deny the second sentence of Paragraph 22 to the extent that it implies that a license directly from Plaintiff would be required to manufacture, distribute, market, and/or sell the Product. Defendants also deny the second sentence of Paragraph 22 to the extent that the term "manufactures" implies something more than processing of the raw ingredients.

23. Defendants admit the first sentence of Paragraph 23. Defendants deny the second sentence of Paragraph 23.

JURISDICTION AND VENUE

24. Paragraph 24 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants deny.

25. Paragraph 25 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants deny.

26. Defendants admit that this Court has personal jurisdiction over them, but otherwise deny the remaining allegations of Paragraph 26.

THE NATURE OF THE ACTION

27. Denied.

28. Admitted.

29. Admitted.

30. Admitted

31. Denied

32. Denied.

33. Admitted.

34. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 34.

35. Denied.

36. Defendants admit the first and second sentences of Paragraph 36. Defendants are without sufficient information or knowledge to admit or deny the allegations of the third sentence of Paragraph 36 that speak solely to Plaintiff's beliefs.

37. Denied.

38. Denied.

39. Defendants admit that NDA did not establish a web site but are without sufficient information or knowledge to admit or deny the balance of Paragraph 39.

40. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 40.

41. Defendants admit that NDA made payments corresponding to the list included in Paragraph 41, but deny the remainder of paragraph.

42. Admitted.

43. Defendants are without sufficient information or knowledge to admit or deny the allegations of the first sentence of Paragraph 43 regarding Plaintiff's knowledge and motivations. Defendants admit that counsel for Plaintiff made contact with NDA's counsel, Frederick Lehrer, and that Mr. Lehrer's letter in response speaks for itself.

44. Defendants admit that Mr. Lehrer wrote a letter dated July 6, 2006 containing the passages quoted in the first and second sentences of Paragraph 44. Defendants deny the remaining portions of the first and second sentences of Paragraph 42. Defendants deny the third sentence of paragraph 44 to the extent that it alleges that NDA or its agents engaged in advertising or informing the public. Defendants are without sufficient information or knowledge to admit or deny the allegations of the third sentence of Paragraph 44 regarding the actions of others.

45. Defendants are without sufficient information or knowledge to admit or deny the allegations of the first sentence of Paragraph 45 regarding Plaintiff's knowledge and motivations. Defendants admit the remaining portions of Paragraph 45.

46. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 46, other than to admit that the email speaks for itself.

47. Admitted.

COUNT ONE – PATENT INFRINGEMENT

48. Defendants incorporate their responses to Paragraphs 1-47.

49. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 49 regarding the actions of others. Defendants deny the remainder of Paragraph 49.

50. Defendants are without sufficient information or knowledge to admit or deny the allegations of Paragraph 50 regarding the actions of others. Defendants deny the remainder of Paragraph 48.

51. Paragraph 51 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants deny.

52. Paragraph 52 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants deny.

53. Defendants are without sufficient information or knowledge to admit or deny the allegations of the Paragraph 53 regarding Plaintiff's belief. Additionally, Paragraph 53 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants deny.

COUNT TWO – BREACH OF CONTRACT

54. Defendants incorporate their responses to Paragraphs 1-53.

55. Denied.

56. Denied.

57. Paragraph 57 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants deny.

COUNT THREE – FRAUD

58. Defendants incorporate their responses to Paragraphs 1-57.

59. Admitted.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

66. Paragraph 66 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants deny.

COUNT FOUR – CONSPIRACY

67. Defendants incorporate their responses to Paragraphs 1-67.

68. Denied.

69. Denied.

70. Denied.

71. Paragraph 71 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants deny.

COUNT FIVE – UNJUST ENRICHMENT

72. Defendants incorporate their responses to Paragraphs 1-71.

73. Denied.

COUNT SIX – DECLARATORY JUDGMENT

74. Defendants incorporate their responses to Paragraphs 1-73.

75. Paragraph 75 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants admit.

76. Paragraph 76 purports to assert legal conclusions to which Defendants are not required to respond. To the extent a response is deemed required, Defendants deny.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Plaintiff has failed to state a claim upon which relief can be granted.

Second Affirmative Defense

Plaintiff's claim of patent infringement is barred by the invalidity and/or unenforceability of the '045 Patent.

Third Affirmative Defense

Some or all of Plaintiff's claims are barred by the doctrine of estoppel.

Fourth Affirmative Defense

Some or all of Plaintiff's claims are barred by the doctrine of laches.

Fifth Affirmative Defense

Some or all of Plaintiff's claims are barred by the doctrine of waiver.

Sixth Affirmative Defense

Some or all of Plaintiff's claims are barred by the doctrine of unclean hands.

Seventh Affirmative Defense

Some or all of Plaintiff's claims are subject to the defense of set-off.

Eighth Affirmative Defense

Plaintiff's breach of contract and declaratory judgment claims are subject to the defense of payment.

Ninth Affirmative Defense

Plaintiff's breach of contract and declaratory judgment claims are barred due to failure of consideration.

Tenth Affirmative Defense

Plaintiff's breach of contract and declaratory judgment claims are barred due to unenforceability or voidness of the contract.

Eleventh Affirmative Defense

Plaintiff's breach of contract and declaratory judgment claims are barred due to frustration of the contract's purpose.

Twelfth Affirmative Defense

Plaintiff's breach of contract and declaratory judgment claims are barred by Plaintiff's breach and/or anticipatory repudiation of the contract.

Thirteenth Affirmative Defense

Some or all of Plaintiff's claims are barred under the doctrine of election of remedies.

Fourteenth Affirmative Defense

Plaintiff's fraud and conspiracy claims must fail due to lack of reasonable reliance.

Fifteenth Affirmative Defense

Plaintiff's fraud and conspiracy claims must fail due to the truthfulness of the alleged misrepresentations.

Sixteenth Affirmative Defense

Some or all of Plaintiff's claims are barred by the statute of limitations.

Seventeenth Affirmative Defense

Plaintiff's conspiracy claim must fail due to the inability of an agent to conspire with his principal.

Eighteenth Affirmative Defense

Plaintiff's breach of contract and declaratory judgment claims are barred by the nonoccurrence of a condition precedent.

Nineteenth Affirmative Defense

Plaintiff has failed to mitigate damages.

Twentieth Affirmative Defense

Plaintiff's fraud and conspiracy claims fail to state the allegations with particularity.

Twenty-First Affirmative Defense

Plaintiff's fraud and conspiracy claims are barred by the economic loss rule.

Twenty-Second Affirmative Defense

Defendants do not infringe, and have not infringed, directly or indirectly, any valid and enforceable claim of the '045 Patent literally or under the Doctrine of Equivalents.

Twenty-Third Affirmative Defense

Plaintiff's claim of patent infringement is barred by license and/or contract.

Twenty-Fourth Affirmative Defense

Plaintiff's claim of patent infringement is barred by patent invalidity arising from an on sale bar.

Twenty-Fifth Affirmative Defense

Plaintiff's claim of patent infringement is barred by the invalidity of the patent claims as being obvious over prior art references and/or anticipated by prior art references.

Twenty-Sixth Affirmative Defense

Any defense raised by any other Defendant relating to the validity of the patent in suit.

Twenty-Seventh Affirmative Defense

The claims of the patent in suit are invalid and unenforceable for not complying with the requirements of 35 U.S.C. § 101, *et seq*.

Twenty-Eighth Affirmative Defense

The claims of the patent in suit are invalid and unenforceable for failure to comply with the applicable rules, regulations, and directives of the U.S. Patent & Trademark Office pertaining to patents.

Twenty-Ninth Affirmative Defense

The claims of the patent in suit are invalid and unenforceable due to Plaintiff's inequitable conduct before the U.S. Patent & Trademark Office during the patent application process.

Thirtieth Affirmative Defense

The claims of the patent in suit are invalid and unenforceable due to Plaintiff's failure to disclosure the best mode of practicing the patent.

Thirty-First Affirmative Defense

Plaintiff's breach of contract and declaratory judgment claims are barred by the fact that Plaintiff fraudulently induced NDA to enter into the license agreement at issue.

COUNTERCLAIM

Defendants/Counterclaim-Plaintiffs, Wellness Industries, Inc. ("Wellness") and Mineral Sciences, LLC ("Mineral Sciences") (hereinafter referred to collectively as "Counterclaim-Plaintiffs"), by and through their undersigned counsel, hereby sue Plaintiff/Counterclaim-Defendant, Lifelink Pharmaceuticals, Inc. ("Lifelink" or "Counterclaim-Defendant"), and state as follows:

General Allegations

1. Counterclaim-Plaintiff, Wellness Industries, Inc., is a Florida corporation with its principal place of business in Parkland, Florida.

2. Counterclaim-Plaintiff, Mineral Sciences, LLC, is a Florida limited liability company with its principal place of business in Research Park Triangle, North Carolina.

3. Counterclaim-Defendant, Lifelink Pharmaceuticals, Inc., is an Ohio corporation having its principal place of business in Stow, Ohio.

4. On June 9, 2000, Harvey Kaufman filed a U.S. Patent Application entitled "Epithelial Cell Cancer Drug (the "Patent Application") which matured into United States Patent Number 6,288,045 on September 11, 2001 (the "'045 Patent" or the "Patent") and listing Lifelink Pharmaceuticals, Inc. as the assignee of the Patent.

5. The Patent Application included "Example 5," and attending charts, describe a five-week mouse study confirming the effectiveness of the patented substance to treat cancer.

6. Contrary to the inventor's and/or patent attorney's representations and assertionsb in the Patent Application, the study in question – completed months before the inventor and/or patent attorney filed the patent application – was actually a seven-week study.

7. That seven-week study, performed by a company called Ricerca, showed that by

week seven the tumor size of mice treated with the patented substance exceeded the tumor size of mice not treated with the patented substance. Also, the results after week five show that the tumors of the mice treated with the patented substance were growing at a rate greater than that of the untreated mouse tumors. These results directly contradict the stated results in Example #5 and seriously call into question the effectiveness of the patented substance to treat cancer.

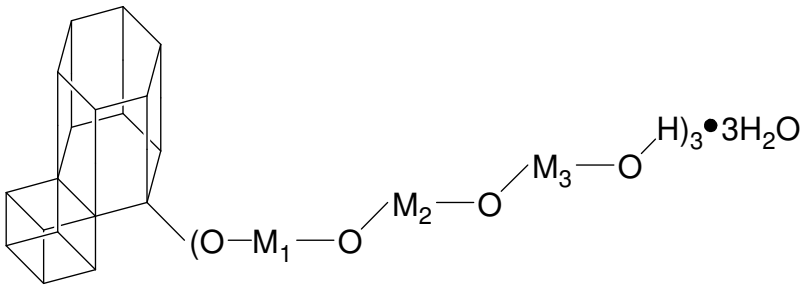
8. At no time did the inventor and/or his patent attorney amend or correct the patent application, or inform the patent examiner, of the complete study results, despite the fact that the complete study results were in the possession of at least the inventor prior to the filing date of the Patent Application.

9. The inventor and/or his patent attorney's affirmative misrepresentations and omissions in the Patent Application regarding the Ricerca study were material, non-cumulative and made with an intent to deceive.

10. The inventor and/or his patent attorney's affirmative misrepresentations and omissions in the Patent Application regarding the Ricerca study amount to inequitable conduct before the United States Patent and Trademark Office ("Patent Office") resulting in the unenforceability of the Patent.

11. The Patent Application, as submitted by the inventor and/or his patent attorney, contains a "Formula I" which purports to describe the chemical formulation of the patented substance and in which the designations "M_1" was represented to be Silicon (or its chemical symbol Si), "M_2" was represented to be Magnesium (or its chemical symbol Mg), and "M_3" was represented to be Aluminum (or its chemical symbol Al). (See '045 Patent, col. 3, lines 47-60; see also diagram below.)

Formula I



12. Formula I describes a chemical moiety, for which the cage portions of the molecule may be construed to be organic or inorganic, either of which violates any scientifically accepted chemical bonding scheme.

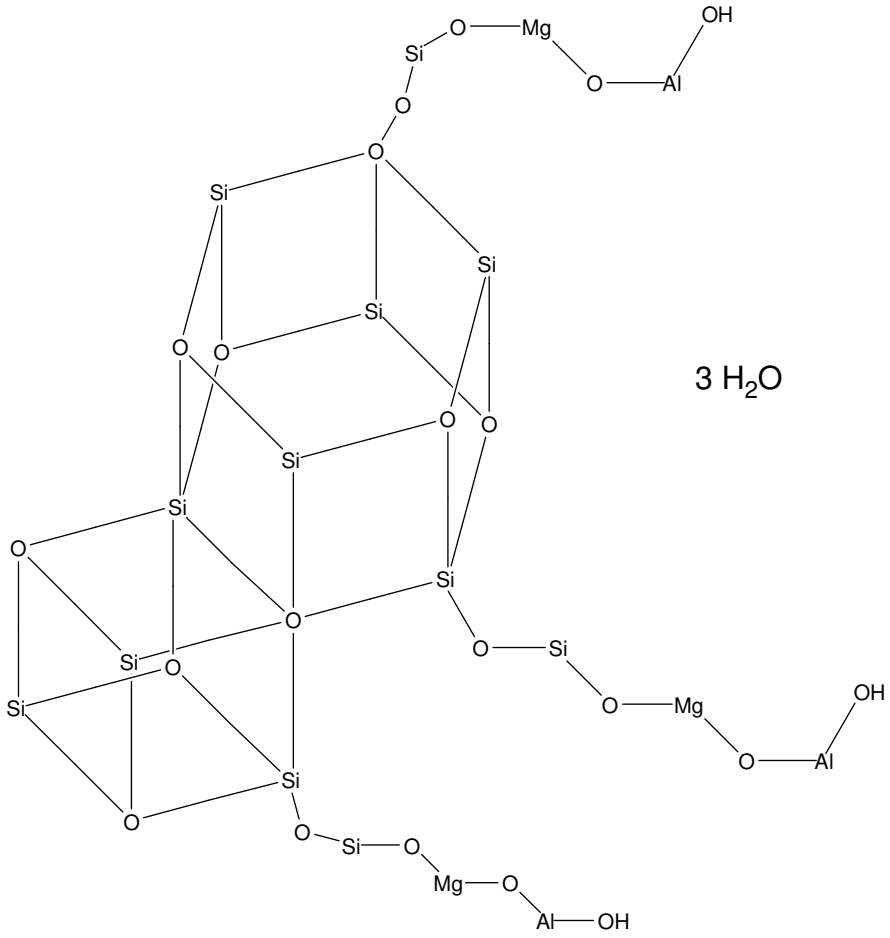
13. Upon information and belief, a review of the patent application history shows that the classification branch of the Patent Office understood Formula I to be an organic molecule, as evidenced by the Patent's United States class/subclass of 514/63 and 556/173 which correlate to organic compound classes. Class 514 relates to drugs, bio-affecting and body treating compositions while subclass 63 relates to subject matter in which the organic active ingredient contains silicon. Class 556 refers to organic compounds while subclass 173 further refines the class of organic compounds to those which refer to silicon compounds.

14. Upon information and belief, a patent's classification guides the Patent Office in forwarding the patent application to the correct art unit with appropriate expertise in the field of science pertinent to the disclosure.

15. Upon information and belief, the patent examiner also believed Formula I to be an organic molecule as evidenced by the Patent's Field of Search in which the patent examiner

searched the organic art class / subclass combinations in order to find prior art pertinent to the disclosure, consistent with the interpretation of the technology described in the patent application, of the Patent Office's classification branch.

16. The inventor understands the patented substance to be inorganic and has testified that when the elements are identified at all vertices of the graphical representation of the molecule, Formula (I) has the following chemical structure.



17. The inventor and/or his patent attorney were informed of the Patent Office's classification of the patent as describing an organic compound no later than August 28, 2000 in the Official Filing Receipt, a document received from the Patent Office less than three months

after the filing of the Patent Application, and did not inform the Patent Office that the classification was in error.

18. The inventor and/or his patent attorney were informed of the specific class / subclass combination no later than March 27, 2001 in the Notice of Allowance and Issue Fee Due Notification, and did not inform the Patent Office that the classification was in error.

19. The inventor and/or his patent attorney were under an affirmative duty to inform the Patent Office of the incorrect classification given to the patent in light of its materiality to the patentability of the subject matter of the Patent Application.

20. Upon information and belief, and regardless of whether the cage structures of Formula (I) are organic or inorganic, the non-cage or "trimetallic tail" sections of the molecule are impossible to synthesize using any of the synthetic procedures described in the Patent.

21. The non-cage component or "trimetallic tail" section of the molecule is not charge balanced and cannot exist. Aluminum has valence of +3, Silicon has a valence of +4 and Oxygen has a valence of -2. Thus, just counting electrons, Formula (I) is illogical from a chemical perspective.

22. Based on the synthetic procedure described in the Patent, it is chemically illogical to conclude that the "trimetallic tail" section of the molecule would have the elements Silicon, Magnesium and Aluminum arranged sequentially as illustrated in the formula when there is no sequential addition of reactants.

23. It is chemically illogical to conclude that there would be two Oxygen atoms bonded together as illustrated in the "trimetallic tail" of the molecule as illustrated at the top of Formula (I).

24. It is chemically illogical to conclude that the cage Oxygen atoms would be

bonded to three Silicon atoms as such a bonding arrangement violates known and accepted chemical bonding rules, despite Mr. Kaufman's testimony to the contrary.

25. The inventor and/or his patent attorney has at various times used the following nomenclature to describe Formula (I) in the Patent, namely 4,5 di-cyclo, disilico, dimagnesium, dialumino, oxyo, trihydrate, 4,6 cyclo, trisilico, trimagnesium, trialumino, oxyo, trihydrate, and 4,5 cyclo, trisilico, trimagnesium, trialumino, oxyo, trihydrate, at times associated with the following anions acetate, sulfate, hydrochlorate, and brominates ("MAS" molecules).

26. The nomenclature employed by the inventor and/or his patent attorney for the MAS molecules follows no chemically accepted syntax (e.g., the International Union of Pure and Applied Chemistry or IUPAC), nor does it provide any structure information as related to Formula (I), nor is it a common name for any chemically known molecule.

27. The European Patent Office informed the inventor and/or his patent attorney on October 27, 2003 that the subject matter of the purported invention was unclear. It specifically stated that "[t]he various definitions of the compounds/compositions claimed (anti cancer drugs) as indicated at different places of the present application appear to be obscure and inconsistent, thus making identification of the compounds doubtful (emphasis added)." The European Patent Office queried "how does the above structural formula (Formula (I) match with the various other definitions, in particular, with those presented in the claims." Further, the Office requested clarification as to "What exactly means "4,5-cyclo", "4,5 cyclo" or 4,6 cyclo"", all of which support inequitable conduct conducted by the inventor and/or his patent attorney before the Patent Office.

28. The European Patent Office informed the inventor and/or his attorney on July 26, 2004 that the subject matter of the purported invention was unclear stating that the "left" cage-

like structural moiety of Formula (I) was not clear as to whether it was organic or inorganic additionally mentioning the issue of the valency of tetravalent silicon and trivalent aluminum, resulting in Formula (I) and all corresponding MAS molecule nomenclature being cancelled from the pending European patent application derived from the United States Patent Application, all of which reveal the inventor's and/or his patent attorney's inequitable conduct before the Patent Office.

29. The inventor and/or his patent attorney's affirmative misrepresentations regarding the nature of the patented substance in the Patent Application and omissions during the prosecution process regarding the classification of the patented substance were material, non-cumulative and made with an intent to deceive.

30. The inventor and/or his patent attorney's affirmative misrepresentations regarding the nature of the patented substance in the Patent Application and omissions during the prosecution process regarding the classification of the patented substance amount to inequitable conduct before the Patent and Trademark Office resulting in the unenforceability of the patent at issue.

31. The Patent Application, as submitted by the inventor and his patent attorney, specifically indicates that the preferred starting zeolite for the synthesis of the patented product is Hydrex R.

32. Hydrex R was not the preferred starting material of the inventor and was used as a starting material in only one experiment out of over hundreds of experiments.

33. Thomsonite was not the preferred starting material of the inventor and was used as a starting material in less than ten (10) experiments.

34. The overwhelming majority of the experiments, i.e., hundreds, conducted by the

inventor in developing the patented substance used clinoptilolite as the starting material.

35. The '045 Patent does not teach the use of clinoptilolite as the starting material in synthesizing the patented substance.

36. The inventor and/or his patent attorney were under an affirmative duty to indicate the correct preferred starting material, or at a minimum, not misrepresent the identity of the preferred starting material which was used in hundreds of experiments conducted by the inventor.

37. The inventor and/or his patent attorney's affirmative misrepresentations regarding the preferred use of Hydrex R and affirmative omissions regarding the preferred clinoptilolite starting material were material, non-cumulative and made with an intent to deceive.

38. The inventor and/or his patent attorney's affirmative misrepresentations and omissions regarding the preferred starting material amount to inequitable conduct before the Patent Office resulting in the unenforceability of the patent at issue.

39. The Patent Application, as submitted by the inventor and his patent attorney, states numerous scientific "facts" and provides five examples "illustrative of the present invention." These facts and examples fail to provide support for the efficacy of the patented product.

40. The Patent Application states that "[i]t is well known that chemicals cause 95% of all cancers contracted by humans." Not only is this statement unsupported, it is unsupportable. No one knows the cause of the overwhelming number of cancer cases.

41. The Patent Application contains five examples, none of which teach the efficacy of the MAS molecule for the treatment of mammalian epithelial cell cancer.

42. Example #1 of the Patent Application purports to demonstrate the functionality of

the Formula (I) by using paper chromatography. Paper Chromatography provides a suggestion of an association only, and is not the equivalent of proof of the inventor's hypothesis, and therefore, does not teach an epithelial cell cancer drug or a method of treating epithelial cell cancer as the example involved the reaction with a component in natural rubber.

43. Example #2 contained in the Patent Application purports to describe a three-year study investigating the effects of adding the patented substance to human cheek cells saturated with saccharin to induce cancer. There is no evidence that sodium saccharin in cell cultures can produce cancer-like changes. The purported proof is conclusory without scientific evidence as the photomicrographs are not proof of any alleged mechanism, and neither is the formation of BLEBS, as normal cells also have BLEBS. This example does not teach an epithelial cell cancer drug or a method of treating epithelial cell cancer

44. Example #2 also states that "100% epithelial cells induced to cancerous state were destroyed within 24 hours," it mentions only a single mechanism for their destruction: "[i]n some cases the cancer cells were destroyed by the outward burst of the cytoplasm by increased osmotic pressure." The mechanism, which logically would affect all cells equally given the same concentration of the patented product, is a physical property that acts independently of the composition of the substance tested. Therefore, the Example #2 study provides no insight into the efficacy of the patented product.

45. Example #3 purports to describe a study testing the effect of the patented product on plant cancer in a certain species of oak tree. Regardless of the outcome of the study, which is unclear, plant cancers are not a model for human cancers. Therefore, the Example #3 study provides no insight into the efficacy of the patented product. The example does not teach an epithelial cancer drug or a method of treating epithelial cell cancer.

46. Example #4 purports to illustrate an example of the use of Formula (I) to treat sodium saccharine induced cancer. First, there is no reported case of human cancer from saccharin use. The only reported cases involved very high doses of saccharin and they studies only employed mice or rats. The purported transition of precancerous cells to cancerous cells which involved a "darkening of the cell cytoplasm" illustrated in the photomicrographs is not a harbinger of cancer, and there is no visual evidence of multinucleation. The example does not teach an epithelial cancer drug or a method of treating epithelial cell cancer.

47. Example #5 contains incomplete (two missing weeks) and misleading data. An analysis of the complete study data actually contradicts the inventor's claims regarding the efficacy of the patented product. The example does not teach an epithelial cancer drug or a method of treating epithelial cell cancer, and when the full seven weeks of data are analyzed, actually teaches AWAY from the invention.

48. Table #3 of the Patent purports to prove that MAS Sulfate is not cytotoxic to cells and that by use of the molecule it is possible to "preferentially target epithelial cancer cells only." There is absolutely nothing in Table #3 to support that conclusion. In fact, Table #3 shows nothing in that there is no osmolality stated in the table, as it is known that physical property is what determines whether a red blood cell will lyse or not. It is further known that hemolytic activity is not related to cancer killing. It is additionally known that red blood cells have no nucleus. As stated in the Patent by the inventor and/or his patent attorney, "the trimetallic portion of the MAS molecule crosses the nucleus of the cancer cell intercalates with the cell mutated DNA and destroys the cancer cell from within." Therefore, any test results with cells without a nucleus are irrelevant to prove the hypothesis of the inventor.

49. The inventor and/or patent attorney's affirmative misrepresentations regarding the

findings and applicability of the studies included as examples as well as in tables, were material, non-cumulative and with an intent to deceive.

50. The inventor's affirmative misrepresentations regarding the findings and applicability of the studies included as examples amount to inequitable conduct before the Patent and Office resulting in the unenforceability of the Patent.

51. Lifelink Pharmaceuticals, Inc., ("Lifelink") purports to be the current owner of the '045 Patent.

52. Beginning in 2003, the principals of Lifelink and NDA discussed proposals for marketing and selling the patented substance.

53. During these negotiations, Mr. Deitsch was provided a copy of the '045 Patent.

54. Also during these negotiations, Mr. Deitsch was informed by principals of Lifelink that the inventor of the patented substance, Harvey Kaufman, was a Ph.D. in chemistry and that Lifelink possessed enforceable patents rights to patented substance. For example, on August 28, 2003, Lifelink faxed Rik Deitsch of NDA a packet of materials which included the patents and documents listing Harvey Kaufman as a Ph.D.

55. The License Agreement was signed on March 9, 2004. In signing the License Agreement, Mr. Deitsch, as the President of NDA, relied on Lifelink's representations regarding (1) Harvey Kaufman's status as a Ph.D. and (2) the fact that Lifelink possessed enforceable patent rights in the patented substance.

56. In signing the License Agreement, Mr. Deitsch also relied on the representations made in the '045 Patent regarding the efficacy of the patented substance.

57. Mr. Deitsch relied on these representations and would not have entered into the License Agreement but for these representations.

58. Harvey Kaufman did not have a Ph.D. degree at the time that he invented the patented substance or at the time that the License Agreement was signed.

59. Due to the inventor's inequitable conduct before the Patent Office at the time of applying for the patent, Lifelink did not, at the time that the License Agreement was signed, possess enforceable patent rights in the patented substance.

60. Many of the representations contained in the '045 Patent regarding the efficacy of the patented substance were false and knowingly false when made.

61. On April 24, 2007, Lifelink filed its First Amended Complaint claiming that the '045 Patent is valid and enforceable and that NDA and Rik Deitsch, among others, infringed on the '045 Patent. Lifelink seeks damages for this alleged infringement.

62. Prior art exists rendering some or all of the formulation and/or method claims of the '045 Patent invalid and/or unenforceable due to obviousness under 35 U.S.C. §103 and/or anticipation under 35 U.S.C. §102.

63. Additionally, the claims of the patent in suit are invalid and/or unenforceable for not complying with the other requirements of Title 35 of the U.S. Code, including but not limited to sections 101, 102, 103, 112, *et seq*.

64. The patent in suit is invalid and/or unenforceable for failure to comply with the applicable rules, regulations, and directives of the Patent Office pertaining to patents.

65. The patent in suit is invalid and/or unenforceable due to the inventor's inequitable conduct before the Patent Office at the time that he was applying for the patent.

66. Pursuant to 28 U.S.C. § 2201(a) the '045 Patent should be declared invalid and/or unenforceable.

COUNT I – DECLARATORY JUDGMENT

67. Counterclaim-Plaintiffs, Wellness and Mineral Sciences, incorporate the allegations of Paragraphs 1 through 66 above of the Counterclaim.

68. This claim seeks a declaratory judgment pursuant to 28 U.S.C. § 2201(a).

69. Due to the suit filed by Counterclaim-Defendant Lifelink, there exists between Counterclaim-Plaintiffs, Wellness and Mineral Sciences, and Counterclaim-Defendant, Lifelink, an actual controversy regarding the validity and effect of the '045 Patent.

70. A judicial declaration of invalidity and/or unenforceability due to the inventor's inequitable conduct before the Patent Office at the time that he was applying for the patent, the application of the on-sale and/or use bar, the existence of prior art, and failure to comply with the other requirements of Title 35 of the U.S. Code, including but not limited to sections 101, 102, 103, 112, *et seq.*, is necessary and appropriate in order to resolve this controversy.

WHEREFORE, Defendants/Counterclaim-Plaintiffs, Wellness Industries, Inc. and Mineral Sciences, LLC, seek (1) a declaratory judgment that some or all claims of the '045 Patent are invalid and/or unenforceable, (2) a declaration that that this is an exceptional case under 35 U.S.C. § 285 and the award of costs, expenses and attorneys fees, and (3) any other relief that this Court deems just and proper.

/s Phillip E. Dubé
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CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2007, a copy of the forgoing Answer to Second Amended Complaint and Counterclaim was electronically filed. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail. Parties may access this filing through the Court's system.

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